REMARKS

Claims 1- 49 are pending. Claims 47-49 are newly added. Support for the amendment to claims 1 and 29 can be found on page 16, line 13.

Applicants would like to thank Examiner Chen and the Examiner's supervisory Timothy Meeks for the interview. The arguments presented and the substance of the interview is reiterated below.

Claims 1-46 have been rejected under 35 U.S.C. § 103(a) as being obvious over Hansen (6,669,980) is view of Bouchier et al. (6,534,112). As correctly pointed out by the Examiner, Hansen discloses application of a coating formulation including a polymer, drug and solvent to a stent such that the evaporation of the solvent produces a coating. Bouchier teaches applying to a medical device an antimicrobial compound and an organic solvent such that the antimicrobial compound is chemically (e.g., covalent boding, van der Waals forces, etc.) or physically (i.e., swell loading) attached to the surface of the device. The device can be made from a polymer such as polyolefin, polyester and silicone (col. 8, line 39). **As explained by Bouchier, the coating process includes exposure of a polymeric medical device to a solvent formulation including a very high concentration of antimicrobial agent so as to allow the antimicrobial to be "imbibed" within the polymer's surface** (col. 8, lines 36-47; *additionally, col. 7, lines 46-55 provide for a similar description. It is important to reiterate, that this section is not teaching blending of a drug with a polymer that is subsequently coated on the medical device, but rather it teaches that the coating includes swelling of a polymer from which a medical device is made to imbibe the drug*). **After the antimicrobial is imbibed, a wash step is used to clean away the solvent and excess, non-imbibed drug**.

Applicants traverse the rejection based on the following grounds:

1. One of ordinary skill in the art would not be motivated to use the wash of step of Bouchier with Hansen's coating since the drug is blended with the polymer. Again, Bouchier uses a "**highly concentrated**" formulation (col. 4, line 27) of an antimicrobial agent to attach as many agents onto a surface of a polymeric or metallic device. The for-

mulation is "highly concentrated" such that not all of the drugs become imbibed in the surface. Accordingly, a wash step is employed to remove the "loose" drugs (col. 9, lines 10-12 provide "**wash solution to aid removing excess antimicrobial deposits that accumulate on the product during coating**"). Hansen does not include any loose or "non –imbibed" drug in need of removal. The method provided by Hansen allows for all of the drugs to be contained in the polymer coating. Therefore, one of ordinary skill in the art would have no motivation to add an extra wash step to Hansen's coating process since there are no "loose" drugs present.

2. Bouchier uses "**toxic**" solvents (col. 4, line 14) that require removal post treatment of the medical device's surface. Again, the medical device of Bouchier is subjected to a "toxic" solvent with excess drug to coat as much drug on the polymer surface of the device as possible. A wash step is needed to remove the toxic solvent and the excess drug. On page 2 of the office action, it is the Examiner's position that all of the solvent is removed from the Hansen coating. Since all of the solvent is removed, then the wash step of Bouchier is not necessary to remove the solvent from the Hansen coating. Should the Examiner argue that some solvent in Hansen is left behind that would require washing, then the Examiner's position that the Hansen coating inherently has less than 2% of residual fluid content cannot be maintained.

3. Hansen teaches a polymeric coating including a drug formed by applying a solvent/drug/polymer solution to the device and allowing the solvent to evaporate. Such coating processes disclosed by references such as Hansen certainly provide a solution to allowing a stent to carry a drug; however, based on the small size of stents and the amount of polymer that can be deposited on stents, adding and maintaining a therapeutically acceptable amount of a drug on stents has been a very difficult challenge. Applicants submit that one of ordinary skill in the art would not be motivated to include an additional wash step since conventional wisdom provides that such a step would lead to removal of the drug from the polymer coating. Considering how difficult it is to add a therapeutically acceptable amount of a drug to a stent, post coating processes that could lead to the removal of the drug would be counterintuitive.

When a dry polymeric coated stent is implanted in a patient, blood causes the drug to leach out of the polymer. Similarly, from the time the coating is made to the time that the stent is implanted in a patient, moisture, humid environment and the like can cause the leaching out of the drug from the coating. As a result, packaging for drug delivery stents is now attracting attention for curing the problem of the drug falling below an acceptable threshold level prior to the stent being implanted in a patient. Accordingly, conventional wisdom provides that subsequent to polymer coating of the stent, the dry coating should be protected from fluids so as to prevent release of the drug from the polymer. Yet, the Examiner is suggesting that this would be a normal step for one of ordinary skill in the art to follow. Applicants with all due respect disagree, considering that what has been claimed is completely contrary to conventional wisdom. The last thing that one skilled in the art would want to do after forming a dry polymeric coating on a stent is to subject the stent to a fluid. Since the coating of Bouchier uses a completely different coating procedure to produce a completely different type of coating, the leaching out of the drug from a polymer coating is not an issue for Bouchier.

4. In the specification, including example 3, Applicants have provided unexpected results -- namely, that the rate of release of the drug actually decreases following a fluid treatment of the polymeric coating and that the rate does not increase based on the leaching or migration of the drug to the surface of the coating. Considering that this is truly an "unexpected result" i.e., completely contrary to what one of ordinary skill in the art would think would occur after exposing a dry coating to a fluid treatment, a *prima facie* case for obviousness should not be maintained.

Applicants believe all the above points were adequately discussed in the interview and that this response provides for an accurate reflection of what was discussed. Based on the interview, it appears that the Examiner, including supervisory Meeks, may be in agreement with the Applicants. Should the Examiner need a better explanation why such combination proposed by the Examiner would not work, Applicants respectfully request a follow-up interview. If the Examiner has any questions or concerns, the Examiner is invited to call the undersigned attorney of record.

Respectfully submitted,

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